DEC - 1 2004

1.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K042476

1.1 Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
Phone: (585) 453-3482
Fax: (585) 453-3368

Contact Person: Carey A. Mayo, M.S., RAC

1.2 Date of Preparation: September 9, 2004

1.3 Device Proprietary Name(s)

Trade Name(s) VITROS Chemistry Products VALP Reagent
VITROS Chemistry Products Calibrator Kit 12
VITROS Chemistry Products TDM Performance Verifier I, II, and III

Common Name Valproic acid assay and controls

1.4 Classification Name(s)

There is no classification regulation for valproic acid. The product code is LEG.
Calibrators: Class II (21 CFR 862.3200)
Assayed Controls: Class I (21 CFR 862. 3280)

1.5 Predicate device

The VITROS Chemistry Products VALP Reagent and Calibrator Kit 12 are substantially equivalent to the SYVA® Emit® 2000 Valproic Acid Assay and the SYVA® Emit® 2000 Valproic Acid Calibrators (Dade Behring, Inc.)
The VITROS Chemistry Products TDM Performance Verifiers are substantially equivalent to the VITROS Chemistry Products TDM Performance Verifiers currently in commercial distribution.

1.6 Device description

The VITROS Chemistry Products VALP Reagent, VITROS Chemistry Products Calibrator Kit 12, and the VITROS Chemistry Products TDM Performance Verifiers are combined by the VITROS 5,1 FS Chemistry System to perform the VITROS VALP assay. VITROS Chemistry Products VALP Reagent is a dual chambered package containing ready-to-use liquid reagents that are used in a two-step reaction to quantitatively measure valproic acid.

VITROS Chemistry Products Calibrator Kit 12 and TDM Performance Verifiers are packaged and sold separately.

VITROS Chemistry Products Calibrator Kit 12 is a liquid ready to use calibrator set for valproic acid. Each kit contains one bottle each of six (6) levels. The level 1 bottle (zero level) contains 5 milliliters. The level 2 through 6 bottles each contain 2 milliliters.

VITROS Chemistry Products TDM Performance Verifier I, II and III are liquid ready to use controls with assayed values published for each lot. The controls are prepared from bovine serum with therapeutic drugs and preservatives added. The product is sold in separate kits of Level I, II and III. Each kit contains 6 vials (2 mL each).

1.7 Device intended use

VITROS Chemistry Products VALP Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products VALP Reagent is used on the VITROS 5,1 FS Chemistry System to quantitatively measure valproic acid (VALP) concentration in human serum and plasma. Serum or plasma valproic acid measurements are used in the diagnosis and treatment of valproic acid overdose and in monitoring levels of valproic acid to ensure appropriate therapy.

VITROS Chemistry Products Calibrator Kit 12: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 12 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of valproic acid (VALP).

VITROS Chemistry Products TDM Performance Verifier I, II and III: For *in vitro* diagnostic use only. VITROS TDM Performance Verifier is an assayed control used to monitor performance of ACET, CRBM, DGXN, PHBR, PHYT and VALP on VITROS Chemistry Systems.

1.8 Comparison to predicate device: Reagent and Calibrators

The VITROS Chemistry Products VALP Reagent and VITROS Chemistry Products Calibrator Kit 12 and are substantially equivalent to the SYVA Emit 2000 Valproic Acid Assay and the SYVA Emit 2000 Valproic Acid Calibrators, which were cleared by FDA (K002551) for IVD use.

The relationship between the VITROS VALP assay and the predicate device, determined by least squares linear regression, is:

VITROS VALP assay = 0.969 X + 1.339 µg/mL, with a correlation coefficient of 0.992, where X is the predicate device.

In addition to the above mentioned correlation study, studies were performed to determine the precision, expected values, linearity, and specificity of the VITROS VALP assay, (refer to the VITROS Chemistry Products VALP Reagent Instructions for Use for summaries of the results of these studies).

The table below lists the characteristics of the VITROS Chemistry Products VALP Assay and the predicate device.

Device Characteristic	VITROS Chemistry Products VALP Assay (New device #1)	SYVA Emit 2000 Valproic Acid Assay (Predicate device #1)
Intended Use	Quantitative measurement of valproic acid	Same
Basic principle	Homogeneous enzyme immunoassay	Same
Reportable Range	10 – 150 µg/mL	1 – 150 µg/mL
Reagents	Liquid ready to use	Liquid ready to use
Instrumentation	VITROS 5,1 FS Chemistry System	SYVA-30R Biochemical System
Sample type	Serum and plasma	Serum and plasma

1.9 Comparison to predicate device: Performance Verifiers

The VITROS Chemistry Products TDM Performance Verifiers are identical in intended use, base matrix, storage and handling and instructions for use as the previously cleared VITROS Chemistry Products TDM Performance Verifiers currently in commercial distribution (K984288). The only difference is the addition of one constituent to the controls. The labeling will be updated to add assigned values for valproic acid so that the TDM Performance Verifiers may be used with the VITROS Chemistry Products VALP assay.

1.10 Conclusions

The data presented in the premarket notification provide a reasonable assurance that the VITROS Chemistry Products VALP assay and the VITROS TDM Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices. Equivalence to the predicates was demonstrated using a commercially available assay along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 1 2004

Ms. Carey A. Mayo, M.S., RAC
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: k042476
Trade/Device Name: VITROS Chemistry Products VALP Reagent
VITROS Chemistry Products Calibrator Kit 12
VITROS Chemistry TDM Performance Verifiers I, II, and III
Regulation Number: 21 CFR 862.3645
Regulation Name: Neuroleptic drugs radioreceptor assay test system
Regulatory Class: Class II
Product Code: LEG, DLJ, DIF
Dated: November 10, 2004
Received: November 12, 2004

Dear Ms. Mayo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K042476

Device Name:

1. VITROS Chemistry Products VALP Reagent
2. VITROS Chemistry Products Calibrator Kit 12
3. VITROS Chemistry Products TDM Performance Verifiers I, II, and III

Indications for Use:

1. For *in vitro* diagnostic use only. VITROS Chemistry Products VALP Reagent is used on the VITROS 5,1 FS Chemistry System to quantitatively measure valproic acid (VALP) concentration in human serum and plasma. Serum or plasma valproic acid measurements are used in the diagnosis and treatment of valproic acid overdose and in monitoring levels of valproic acid to ensure appropriate therapy.
2. For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 12 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of valproic acid (VALP).
3. For *in vitro* diagnostic use only. VITROS TDM Performance Verifier is an assayed control used to monitor performance of ACET, CRBM, DGXN, PHBR, PHYT and VALP on VITROS Chemistry Systems.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042476